

35. (New) A method for forming a biological extract as recited in claim 33, wherein said solvent of said mixing step (a) is ethyl acetate.

REMARKS

(1) The amendment to the specification is in response to the Examiner's office action, dated April 4, 2002. Specifically, the specification was objected to for missing text. The above amendment corrects the typographical error. Please note that the added text is commensurate with subject matter repeatedly discussed throughout the text and does not constitute new matter.

(2) The amendment to claim 1 has been made to better define the subject matter of the invention. Support for the amendment can be found on page 10 and pages 14+ of the specification.

(3) New claims 30-35 have been added in response to issues raised by the examiner in the Office Action dated April 4, 2002, and also issues raised and suggestions given by the examiner during the personal interview conducted with the examiner, dated August 20, 2002. The new claims were added to better define the subject matter of the new invention. Consequently, the newly added claims do not constitute new matter. Support for the amendment to the claims can be found on pages 14-16 of the specification.

(4) Applicants wish to thank the examiner for the interview of August 20, 2002. This amendment is responsive to the office action dated April 4, 2002, and is commensurate with the discussions conducted during the interview. The following is a response to issues raised by the examiner's office action and subsequent interview.

A. Examiner's rejection of claim 1, under 35 USC 112, 1st paragraph.

The examiner states that the specification is not enabling for claims drawn to a biologically active extract, particularly to "any and all biological activities" for the plant extract using "any and all solvents," as there is no guidance "other than an ethyl acetate or methanolic extract of the seeds of *Napoleonaea imperialis*," and therefore would require "undue experimentation without a reasonable expectation of success to determine which plant extracts would exert which biological activities, wherein the plant extract is prepared using any and all solvents, and any all plant parts thereof, other than those demonstrated...."

Applicants respectfully traverse this rejection. It is not the applicants' intent to claim any and all biological extracts using any and all solvents. Rather, applicants' claim 1 broadly recites the biological extracts of a group of plants. In support, the specification provides experimental data for all claimed plant species and the biological activities they assert. The detailed description begins with the manner of collecting of these plants and continues detailed procedures for testing, including the types of solvents uses, and the results obtained. The bioassay process and results for *Napoleonaea imperialis* are described in pages 14-16, lines 30+ and pages 24-25, lines 6+.

The rule regarding undue experimentation does not require an applicant to compile a production specification disclosing all possible means and modes of testing. Secondly, the degree of enablement required must bear a *reasonable correlation* to the scope of protection sought by the claims. In the present instance, the fact that the specification particularly points to testing the seeds of *imperialis* does not preclude broad claims recitation of “biological active extracts,” because there is sufficient guidance in the specification that plant extracts from various parts of the claimed plants are desirable. (See page 10, lines 34+.) Applicants’ specification provides sufficient enablement to one of ordinary skill to carry out the invention, and, furthermore, is reasonably related to the claims being recited. Additionally, applicants have amended claim 1 to better define the invention. Therefore, the examiner’s assertion that the specification does not enable the claims is without merit.

B. Examiner’s rejection of claims 1-12 under 35 USC 112 2nd paragraph as being vague and indefinite.

The examiner states that the claimed subject matter would be “best defined” as product-by-process claims, as they “are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art).” The examiner further states that, “since the extract itself is clearly essential to the claimed invention, the step(s) by which the claimed extract is obtained are also clearly essential, and therefore, must be recited in the claim language itself (i.e., as a product-by-process).”

The examiner’s arguments are respectfully traversed. As the examiner correctly stated during the examiner’s interview, patentability of a product-by-process claim is

limited to the product itself. Therefore, the examiner's assertion that essential steps would clearly distinguish the product from the prior art is without merit. "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (See *in re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985))

It is also clear from the examiner's statements shown above that she recognizes that the steps in making the biological extract are essential to the claimed invention. However, the examiner requested that method claims existing in the originally filed application be restricted. Applicants, in good faith, chose to elect the composition claims (without traverse), as they felt that the examiner's position on restriction bore merit. However, the examiner's subsequent office action provides that she views the process by which the composition is made is essential to the applicants' claimed invention. This position is in contradiction to the restriction requirement. In view of the examiner's position on process steps, with which applicants concur, applicants respectfully request that the restriction to the method claims be withdrawn, and the newly added claims drawn to the method be examined.

C. The examiner's rejection of claims 1 and 11-12 under 35 USC 102(b) as being anticipated by Mbah, et al.

The examiner's rejection is respectfully traversed. As discussed in the personal interview, Mbah, et al., are specifically directed to extracting the leaves, stems, stem bark, root and root bark of *Napoleonaea imperialis* (using ethanol, acetone and chloroform) for treatment of cough and gastrointestinal disorders. The use of herbal

treatments using indigenous plants is well known in African traditional medicine. Applicants' specification teaches the use of several plants and their efficacies in treating diseases (See page 4, lines 21 +). Mbah, et al., is an initial test mechanism that concludes "crude extracts of leaves, root bark and stem bark of *N. imperialis* exhibited some antibacterial properties, thus supporting the use of the plant in traditional medicine." There is no hint, let alone any teaching, that anticipates or makes obvious applicants' claimed invention directed to extraction of *N. imperialis* for the purposes of treating parasitic or fungal infections, using the solvents disclosed by applicants, nor any teachings as to the methodology or testing detailed in the specification and claims of the applicants' invention.

The examiner concurred with applicants' argument regarding the distinction between Mbah, et al., and the applicants' invention, but indicated that the rejection was made due to the broad recitation of the claim language. Applicants' have amended claim 1 above to better define the subject matter of the present invention, and distinguish their invention from the teachings of Mbah, et al.

For the reasons given above, it is the applicants' position that the claims, as amended, overcome the examiner's rejections. Early allowance of the claims is respectfully solicited.

Please send all correspondences to: Elizabeth Arwine, Esq.; Office of the Staff Judge Advocate; U.S. Army Medical Research & Materiel Command; 504 Scott Street, Fort Detrick, MD 21702-5012; Attn: MCMR-JA (Ms. Arwine).

Please direct any questions regarding this case to Abanti B. Singla at (301) 620-4070.

Sept. 4, 2002
Date

Sincerely,

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